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Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20205



Aquasearch Inc.  
Kona Production Facility  
73-4460 Queen Kaahumanu Highway  
Suite 110, Kailua-Kona, HI 96740 USA  
Tel: (808)326-9301 Fax: (808)326-9401  
WebSite: <http://www.aquasearch.com/>  
E-mail: [aqse@aquasearch.com](mailto:aqse@aquasearch.com)

December 6, 1999

Re: New Dietary Ingredient Notification for *Haematococcus* algae.

Dear Administrator,

Pursuant to rule 21 CFP Subpart B 190.6, please be advised of this New Dietary Ingredient Notification for *Haematococcus pluvialis* algal meal. Throughout this application, terms such as *Haematococcus pluvialis*, *H. pluvialis*, *Haematococcus*, are to be considered equivalent and interchangeable.

We plan to market *Haematococcus* algae as an ingredient for human dietary supplements, 75 days after the acknowledgement of receipt of this notice, unless otherwise instructed by your agency.

Please find enclosed one original and two copies of this notification.

We presently produce an algal meal prepared from *Haematococcus*, which we market as a feed ingredient in Europe and in Asia, for application in fish and poultry diets. This product is stabilized with ethoxyquin.

The product which we plan to market will be an algal meal prepared at our facility in Kona. It will not be stabilized with ethoxyquin but may be sold as is or stabilized with an approved natural food-grade antioxidant, such as natural vitamin E, grapeseed extract, or an equivalent approved antioxidant.

The algal meal may be used as an ingredient in tablets, capsules or other dietary supplement preparations. It may also be used as a base for further extraction with approved food-grade solvents and extraction processes, to recover some of the active components, such as natural astaxanthin and other pigments.

The algal meal will be manufactured by:

Aquasearch, Inc.  
73-4460 Queen Kaahumanu Hwy., Suite #110,  
Kailua-Kona, Hawaii 96740,  
Tel: (808) 326 – 9301, Fax: (808) 326 – 9401

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The scientific name of the dietary ingredient subject to premarket notification, is the Latin specific name, *Haematococcus pluvialis*, or the Latin generic, *Haematococcus*.

A trademark may precede this generic scientific name, such as: Nutraxan™Asta or the AstaFactor™.

Information on the origin, manufacturing process and specifications, as well as proposed labeling and usage recommendations, has been provided in the attachments (Section 2).

A daily serving of 5mg astaxanthin and/or 250 mg algal meal, in one or two tablets or softgels is suggested.

There has been already significant information made public to support the safety of astaxanthin and of *Haematococcus* as a dietary supplement (see Section 5 for details), including a New Dietary Ingredient Notification for *Haematococcus* algae, from Cyanotech Corporation, submitted to FDA on March 18, 1999. In addition, antioxidant properties of astaxanthin and its metabolic effects have been widely investigated (see Section 6) and give no reason to believe that there should be any safety concern when ingested at the recommended levels (see Section 5 for details). We feel that Aquasearch's unique proprietary production technology and the well documented safety studies conducted on our product (Section 5), provide unique additional information to confirm that algal astaxanthin and, more broadly, *Haematococcus* produced with Aquasearch's technology, is safe when used as an ingredient for dietary supplements according to the appropriate recommendations.

We contend that this product is a natural product which is unadulterated and meets the evidence of safety under the Federal Food, Drug and Cosmetic Act sec. 413 (350b)(a)(2).

Furthermore the product is produced under strict quality control and according to current dietary supplement GMP recommendations, with quality checks throughout manufacturing and after processing.

Thank you very much in advance for the attention that you will give to our notification. If you have any question, do not hesitate contacting us at (808) 326-9301.

Sincerely yours,

  
Martin Guérin  
V.P. Marketing & Sales  
Aquasearch Inc.

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